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10/597,991	06/21/2007	Eric James Wall	CHM-021M	8880

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EXAMINER	
PRICE, NATHAN R	

ART UNIT	PAPER NUMBER
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,991	WALL ET AL.	
	Examiner	Art Unit	
	NATHAN R. PRICE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This office action is responsive to the amendment filed on April 27, 2009. As directed by the amendment: claims 1, 2, 5, 10, 11, and 20 have been amended, claim 16 has been cancelled, and new claim 21 has been added. Thus, claims 1-15 and 17-21 are presently pending in this application. Applicant's amendment to claim 20 is sufficient to overcome the objection to the claim from the previous action.

Claim Objections

2. Claim 9 is objected to because of the following informalities: "wherein the separable base **comprising**" should be amended to "wherein the separable base **comprises**". Appropriate correction is required.

3. Claim 21 is objected to because of the following informalities: "the injecting means" lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 2, 10, 11, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar (US 5527287) in view of Woehr et al. (US 20030144627).

6. Regarding claims 1, 2, 10, and 11, Miskinyar discloses a manually-powered injection device for painless inter-muscular injection of an injectable liquid composition

from with a reservoir, comprising: a housing 84 (fig. 8-9) having a base for semi-permanent attachment to the skin of a patient (col. 5, ln. 11-14), an injection needle 94 (fig. 8-9) disposed substantially perpendicular to the base and within the housing (see fig. 8), the needle having an injection end (distal end, fig. 8-9), and configured for axial movement manually between a first position (shown in fig. 8) wherein the injection end is within the housing and a second position (shown in fig. 9) wherein the injection end extends outwardly from the base to a distance sufficient for intramuscular insertion thereof (see fig. 9), a means for retaining a reservoir containing an injectable liquid composition (ring 116 retains reservoir 98 in retracted position prior to use, fig. 8), a means for providing liquid communication between the retained reservoir and the injection needle (proximal end of needle 94 is held in communication with reservoir 98 via its attachment to carriage 96, fig. 8), and a means for injecting the injectable liquid composition from the retained reservoir through the needle, wherein the means for injecting is a manually-powered spring 128 (fig. 8-9) that is configured to exert pressure upon the injectable liquid composition within the retained reservoir and is configured to inject the injectable liquid at a substantially constant volumetric flow rate (via spring 128, fig. 8-9), **except** for the injection needle having an outside diameter greater than 0.10 mm and less than about 0.38 mm and a constant volumetric flow rate of about 0.5 µL/s to about 20 µL/s. However, Woehr et al. teaches injection needles with diameters in this range (see table 1, page 5, which specifically mentions needle outer diameters of .3 mm, .33mm, and .35 mm). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Miskinyar

apparatus such that the injection needle has an outside diameter greater than .10mm and less than about .38 mm, as taught by Woehr et al., for the purpose of providing a needle of sufficiently sized diameter to require an appropriate application of strength for use (par. 0079, table 1).

7. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to inject at a volumetric flow rate of about 0.5 µL/s to about 20 µL/s, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

8. Claims 3-8 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of McWethy et al. (US 7004929).

9. Regarding claims 3-8 and 12-17, Miskinyar in view of Woehr et al. discloses the apparatus as claimed, including means for retracting the injection needle (spring 102, fig. 8), whereby the injection end of the needle can be retracted from its second position to a third position wherein the injection end of the needle is within the housing, a needle carriage 96 (fig. 8-9) to which the injection needle is affixed, the needle carriage being configured for axial movement between a first position associated with the first position of the injection needle, and a second position associated with the second position of the injection needle, in response to a manual force applied by a person (usage described in col. 5, ln. 9-27), and an implement (button 104, fig. 8-9) for use in applying the manual force to the needle carriage, **except** for a needle insertion securement configured to

retain the inserted needle in its second position while injecting the fluid composition, configured to retain the needle carriage in its second position, a retracting means comprising a disengagement means configured to disengage the needle insertion securement from the needle carriage, and a power means configured to bias the needle carriage to a third position that is associated with a third position of the injection needle wherein the injection end of the needle is within the housing. However, McWethy et al. teaches a needle insertion securement (comprising arm 26 and latch 27, fig. 4) configured to retain the inserted needle in its second position while injecting the fluid composition (col. 5, ln. 48-67), configured to retain the needle carriage in its second position, a retracting means comprising a disengagement means 46 (fig. 5) configured to disengage the needle insertion securement from the needle carriage (col. 6, ln. 11-41), and a power means 24 (fig. 4-5) configured to bias the needle carriage to a third position that is associated with a third position of the injection needle wherein the injection end of the needle is within the housing (col. 6, ln. 11-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Miskinyar in view of Woehr et al. apparatus such that a needle insertion securement is configured to retain the inserted needle in its second position while injecting the fluid composition, configured to retain the needle carriage in its second position, a retracting means comprises a disengagement means configured to disengage the needle insertion securement from the needle carriage, and a power means is configured to bias the needle carriage to a third position that is associated with a third position of the injection needle wherein the injection end of the needle is within

the housing, as taught by McWethy et al., for the purpose of maintaining insertion of the needle in the patient (abstract).

10. Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al., and further in view of Flaherty (US 6749587).

11. Regarding claims 9 and 20, Miskinyar in view of Woehr et al. discloses the apparatus as claimed, including a base comprising an adhesive for attachment thereof to the skin of a patient (col. 4, ln. 18-23), **except** for a separable base, a base securement means configured for separable securement of the separable base to the housing, and a base separation means configured for separation of the separable base from the housing. However, Flaherty teaches a separable base and base securement means (fig. 9; col. 17, ln. 3-15; abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Miskinyar in view of Woehr et al. apparatus such that it comprises a separable base, a base securement means configured for separable securement of the separable base to the housing, and a base separation means configured for separation of the separable base from the housing, as taught by Flaherty, for the purpose of allowing part of the apparatus to be reused (abstract).

12. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskinyar in view of Woehr et al. and McWerthy et al., and further in view of Landau (US 6264629).

13. Regarding claims 18 and 19, Miskinyar in view of Woehr et al. and McWerthy et al. disclose the apparatus as claimed **except** for the carriage and reservoir comprise

cooperating threads that engage and retain, a penetrable membrane, and a piercing conduit to penetrate the penetrable membrane. However, Landau teaches for a carriage and reservoir comprising cooperating threads that engage and retain (col. 5, ln. 25-28), a penetrable membrane 82c (fig. 5), and a piercing conduit 80 (fig. 5) to penetrate the penetrable membrane of the reservoir. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Miskinyar in view of Woehr et al. and McWerthy et al. apparatus such that the carriage and reservoir comprise cooperating threads that engage and retain, a penetrable membrane, and a piercing conduit to penetrate the penetrable membrane, as taught by Landau, for the purpose of allowing use of the apparatus with conventional pre-packaged medications.

Response to Arguments

14. Applicant's arguments filed April 27, 2009 have been fully considered but they are not persuasive.

15. Applicant argues on page 7 of the Remarks, that Miskinyar fails to disclose a "manually-powered injection device" and a device for "painless intramuscular injection". First, the recitations "manually-powered" and "painless intramuscular injection" which are found in the preamble have not been given patentable weight because the recitations occur in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand

alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Furthermore, Examiner interprets "manually powered" broadly to include any apparatus which requires manual application of force in order to actuate; Miskinyar's apparatus clearly requires a manual actuation force in order to power an injection (see col. 5, ln. 16-20) in the form of pushing a button. Finally, the functional limitation "painless" may be interpreted very broadly, as pain threshold varies from one individual to another, from one species to another, and from one injection site to another. A recitation of the intended use of the claimed invention (administering a "painless" injection) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Examiner maintains that the Miskinyar apparatus is capable of administering a painless injection, especially to a subject or injection location with a high pain threshold.

16. Applicant further argues on page 7 of the Remarks that no embodiment of Miskinyar discloses both "a range of needle lengths sufficient for intramuscular injection" and a "base for semi-permanent attachment to the skin". Once again, the limitations "for semi-permanent attachment to the skin of a patient" and "a distance sufficient for intramuscular insertion thereof" are functional intended use recitations. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the

intended use, then it meets the claim. Since a needle length required for "intramuscular injection" would vary from one individual to another, from one species to another, and from one injection site to another, Examiner maintains that the Miskinyar apparatus relied upon in the rejections above is capable of performing an intramuscular injection, especially to a subject or injection location having a required depth corresponding to the needle length of the apparatus. Furthermore, Examiner cited col. 5, ln. 11-14 regarding the limitation of “semi-permanent attachment”. In addition to this citation, Examiner notes that “semi-permanent" attachment is broad enough to encompass any way in which the apparatus could be made to stay in place at the injection site. Any apparatus with a needle, if inserted at an injection site, is technically semi-permanently attached to the skin, since if released it would stay in place on the subject, and it must instead be manually removed by the person administering the injection.

17. Applicant argues on pages 7-9 that Woehr et al. does not describe the use of any particular needle size or address the problem of pain caused by the use of larger-diameter sized needles during intramuscular needle insertion, that there is no rational basis to combine the teachings, and the rejection employs hindsight to combine specifically selected features from the teachings of the references. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only

from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Examiner maintains that Woehr et al. teaches ranges of commonly used needle diameters, including those claimed, from which Woehr indicates one of ordinary skill in the art at the time the invention was made would know to select based on desired push and pull strengths required for injection (see par. 0079, 0080, and Table 1). Regarding Applicant's remarks in reference, once again, to the limitations involving "painless" injection, see arguments above.

18. Applicant claims on pages 9-10 of the Remarks that the rejection of claims 4-6 and 13-15 is unclear. However, from Applicant's arguments, it appears that Applicant has had no trouble interpreting the rejections as presented. The claims are rejected under 35 U.S.C. 103(a), as with the independent claims on which they depend, because of the limitation from the independent claims for which the Woehr et al. reference was relied upon.

19. Regarding Applicant's arguments on page 10 regarding claims 4 and 13, the behavior of spring 102 during injection does not preclude its ability to function as a retraction mechanism after injection has been completed.

20. Regarding Applicant's arguments on page 10 regarding claims 5 and 14, and 6 and 15, see arguments above regarding the "manually-powered" limitations.

21. On page 11 of the Remarks, Applicant expresses some confusion regarding the Examiner's method of citing a rejection under 35 U.S.C. 103(a), since Examiner cited the claims "verbatim" and added "figure references and text passages from McWethy in parentheses". The format used is chosen specifically so that the claim limitations are each addressed exactly as they are presented by applicant. Though the format may seem redundant to Applicant, the limitations are rejected with pertinent citations to the prior art for clarity.

22. Regarding Applicant's argument regarding claims 3 and 12, and claim 7, and claims 8 and 17 on pages 12 and 13, Applicant seems to import limitations from the specification in support of the argument that McWethy does not disclose the claimed apparatus. Examiner cited fig. 4, specifically elements 26 and 27, which McWethy states "maintain the needle in the extended position" (col. 5, ln. 48-50). Examiner does not simply refer to a complicated assembly, as Applicant alleges, but has cited particular elements of the McWethy apparatus which meet the limitations of the claims in question, and cited the pertinent section of the disclosure which describes the function of the cited elements. Examiner further provided motivation for combining the references at the end of paragraph 6.

23. Regarding Applicant's argument on page 13 of the Remarks regarding claims 9 and 20 that element 800 of Flaherty "is not a separable base". The limitation "base", however, does not import any specific limitations that preclude the application of

Flaherty element 800 as a "base", and Applicant has provided no evidence of how element 800 of Flaherty does not function as a base.

24. Regarding Applicant's argument on page 14 of the Remarks regarding claims 18 and 19, the structure of a piercing member operable to penetrate a membrane to establish liquid communication between two elements as claimed is present in the Laundau reference, as cited in the previous rejection and the rejection above.

Conclusion

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is

(571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./
Examiner, Art Unit 3763

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